UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA

UNITED STATES OF AMERICA, Plaintiff, v. GUIDANT LLC, Defendant.	Criminal No. **10-MJ-067** **GOVERNMENT'S POSITION REGARDING SENTENCING**

I. INTRODUCTION

The United States of America, by and through its counsel, the Office of the United States Attorney for the District of Minnesota, and the United States Department of Justice, Office of Consumer Litigation (collectively, the "Government"), hereby submits this memorandum to present its position on sentencing.

Guidant LLC ("Guidant")[1] has pleaded guilty to both counts of the Information charging it with violating the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301 *et. seq.*) ("FDCA"). The Government believes that the stipulated penalty, $296,041,926 in criminal fines and forfeiture is an appropriate resolution to this case.

The plea resolves a four-year investigation into the events leading up to and surrounding Guidant's highly-publicized recalls of three models of implantable defibrillators during June 2005. The devices were known as the Ventak Prizm 2 DR, the Contak Renewal, and the Contak

[1] Boston Scientific Corporation acquired Guidant Corporation on or about April 21, 2006, at which time Guidant Corporation became a wholly-owned subsidiary of Boston Scientific. On or about February 19, 2010, Guidant Corporation became a limited liability company organized under the laws of Indiana and was renamed "Guidant LLC."

Renewal 2. The devices' flaws, which came to light only in the wake of a front-page exposé published in the NEW YORK TIMES, have been responsible for at least thirteen deaths. The thirteenth death associated with a Contak Renewal short-circuiting was reported to FDA only five months ago.

II. THE CRIMINAL CHARGES

Guidant has pleaded guilty to two separate counts of violating the FDCA. Count One of the information charges Guidant with making false and misleading statements in a required report to FDA in violation of 21 U.S.C. §§ 331(q)(2), 333(a)(1) with regard to the Prizm 2. Count Two charges Guidant with failing to report to FDA a correction, *i.e.*, a recall, with regard to the Renewal line of devices it undertook in an effort to mitigate the serious risk to public health and safety the misbranded devices posed. Such a notification to FDA is required by 21 U.S.C. § 360i(g) and the failure or refusal to make such notification is prohibited by 21 U.S.C. §§ 331(q)(1)(B) and 333(a)(1).

A. Regulatory Background

As the information explains, the FDCA governs the manufacture, processing, packing, labeling, and shipment in interstate commerce of medical devices designed for human use. The FDCA, and its implementing regulations, require that medical device manufacturers submit certain reports, notifications, and applications to the United States Food and Drug Administration ("FDA") with regard to medical devices. 21 U.S.C. §§ 360h; 360i; 360j. Such required notifications include a requirement that a manufacturer of a medical device promptly report any correction or removal of a medical device if the removal or correction was undertaken to reduce a risk to health posed by the device, or to remedy a violation of the FDCA caused by the device which may present a risk to health. 21 U.S.C. § 360i(g). In addition, the FDCA prohibits the

submission of any required report relating to medical devices that is false or misleading in any material respect. 21 U.S.C. § 331(q)(2).

All medical devices fall into one of three classes, based on their risk to the health, safety, or welfare of the patient. Class III medical devices, like the devices at issue in this case, are the most highly-regulated class, and are intended for use in supporting or sustaining life, are of substantial importance in preventing impairment of health, or present a potential unreasonable risk of illness or injury.

Generally, Class III medical devices may not be marketed in the United States without FDA approval of a Pre-Market Approval ("PMA") application submitted by the device manufacturer. The PMA application must provide FDA with sufficient information to demonstrate that there is reasonable assurance that the device is safe and effective for its intended use and under its proposed labeling.[2] Once FDA has approved a device application, the device may be manufactured and distributed only under the conditions approved in the approval.

Ordinarily, the device and its labeling cannot be lawfully modified in any manner that affects the safety or effectiveness of the device unless the manufacturer files, and receives FDA approval for, a supplemental PMA ("SPMA"). 21 C.F.R. § 814.39(a). As a result, changes to device labeling that have been brought about by unanticipated adverse events, increases in the incidence of anticipated adverse events, or device failures must be submitted to FDA for prior approval. This requirement ensures that the FDA is alerted to, and is able to evaluate, the risks to public health that are prompting the proposed changes. Unlike changes to the device that affect safety and effectiveness, which must be specifically submitted to FDA for prior approval,

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[2] Labeling includes all written, printed, or graphic material that is on a device or on its container or distributed by the manufacturer or supplements or explains the uses or manner of use of the product. *See* 21 U.S.C. § 321(m). Labeling generally includes anything written by the manufacturer which reaches the physician or patient, and which supplements or explains the product before, with, or after the product is distributed.

a manufacturer may report non-safety and effectiveness related changes in a periodic post-approval report to FDA. 21 C.F.R. § 814.39(b). Typically, these reports are required to be submitted annually, and are referred to as "annual reports."

FDA has the authority to order a manufacturer to undertake various actions to remedy a violation of the FDCA, especially with regard to a device that poses a risk to public health. The manufacturer may also voluntarily take certain actions with regard to devices that violate the FDCA or that pose a risk to health. In the parlance of the FDCA and its regulations, these actions are either "removals" or "corrections," depending upon whether the device is removed from its point of use:

> *Correction* means the repair, modification, adjustment, relabeling, destruction, or inspection (including patient monitoring) of a device without its physical removal from its point of use to some other location.
>
> * * *
>
> *Removal* means the physical removal of a device from its point of use to some other location for repair, modification, adjustment, relabeling, destruction or inspection.

21 C.F.R. § 806.2. The removal or correction of a device that the agency considers to be in violation of the FDCA and against which the agency would initiate legal action is called a "recall." 21 C.F.R. § 7.3(g).

B. Factual Summary

Beginning in or about 1994 and through the time of its acquisition by Boston Scientific, Guidant engaged in the development, manufacture, processing, packaging, sale, marketing, and interstate distribution of implantable cardioverter-defibrillators ("ICDs"). A specialized type of ICD used in the treatment of heart failure is known as a cardiac resynchronization therapy-defibrillator, or "CRT-D." Guidant's ICDs and CRT-Ds treated, among other things, conditions

in the human heart that can cause sudden cardiac death. ICDs and CRT-Ds prevent sudden cardiac death by constantly monitoring the electrical activity in a patient's heart for potentially lethal rhythms such as ventricular tachycardia and ventricular fibrillation. Upon detecting such dangerous rhythms, the ICD or CRT-D delivers an electrical shock to the heart in an effort to return the heart to a normal rhythm. If these devices fail to operate properly when needed, the patient can die within just a few minutes.

In 2002, Guidant became aware that its Prizm ICD was prone to electrical arcing, rendering the device inoperative and unable to deliver therapy to the patient in whom it was implanted. Loss of therapy can be fatal. Guidant initiated two separate corrective actions in the form of manufacturing and design changes to the Prizm in April 2002 and November 2002. Guidant did not report the April 2002 change to FDA at all. The November change was described in a post-approval annual report to FDA in August 2003, but did not describe the arcing problem the change was intended to correct. Furthermore, Guidant falsely stated in the report that the November change did not affect the safety, efficacy, or performance of the device. Indeed, the entire purpose of these changes was to affect the Prizm's safety and efficacy and correct a serious device flaw. These facts form the basis of the first count of the information, which charges Guidant with making materially false and misleading statements in required reports.[3]

In late 2003, Guidant discovered a similar arcing problem with its Renewal family of ICDs. By July 2004, Guidant had determined that the Renewal's existing labeling was false and misleading with regard to the presentation of this particular failure. Although it ordered its factory to stop building or shipping Renewals due to seriousness of the devices' defect on or

[3] After it had implemented these corrective actions, Guidant continued to implant almost 7,000 Prizm devices that had been manufactured prior to the changes. In fact, Guidant did not communicate any information about this defect to physicians generally until the device was recalled in mid-2005, following the high-profile death of a 21-year-old patient described below.

about August 25, 2004, the company also explicitly directed that any defective devices that had already left the factory continue to be implanted into patients.[4]

Guidant failed to notify the FDA or physicians regarding both the risk of device arcing as well as the false and misleading labeling until after the devices were recalled in June 2005. Instead, in March 2005, Guidant sent a communication to physicians called a "Product Update" in an attempt to reduce the risk to health that the false and misleading labeling presented. Rather than report this action to FDA as was legally required, Guidant instead made false and misleading statements to FDA throughout the spring of 2005 in an effort to conceal what amounted to a stealth recall of the Renewal CRT-D. The failure to make the appropriate reports to FDA of this "correction" is the basis for the second count of the information.

As of October 2010, there have been thirteen known deaths associated with these failures, but it is likely that there have been several other deaths that were never reported to the company. This is because a patient with a failed device who suffers ventricular fibrillation outside a hospital setting will likely die from the event and often no detailed investigation or analysis of the implanted device is conducted; the patient will not return to the office or hospital to have the device interrogated, and no adverse event report will be submitted to FDA.

III. THE ESSENTIAL ELEMENTS OF THE OFFENSES

A. Count One: False Statements in Required Submission

Section 331 of Title 21, United States Code, lists prohibited acts, including:

> "(q)(2) With respect to any device, the submission of any report that is required by or under this chapter that is false or misleading in any material respect."

[4] In all, 163 defective Renewals were implanted in the United States after Guidant ordered its factory to halt production. Roughly 200 more were implanted outside the United States during this period.

21 U.S.C. § 360i(a) permits the Secretary of Health and Human Services to promulgate regulations requiring manufacturers of medical devices intended for human use to "make such reports, and provide such information . . . to assure that such device is not adulterated or misbranded and to otherwise assure its safety and effectiveness."

21 U.S.C. § 814.39(a) states that a device manufacturer:

> [S]hall submit a PMA supplement for review and approval by FDA before making a change affecting the safety or effectiveness of the device. . . Changes for which an applicant shall submit a PMA supplement include, but are not limited to, the following types of changes if they affect the safety of the device. . .
>
> (6) Changes in the performance or design specifications, circuits, components, ingredients, principle of operation, or physical layout of the device.

21 C.F.R. § 814.39(b) permits non-safety related changes to be reported in periodic post-approval reports to FDA submitted by the device manufacturer:

> An applicant may make a change in a device after FDA's approval of a PMA for the device without submitting a PMA supplement if the change does not affect the device's safety or effectiveness and the change is reported to FDA in postapproval periodic reports required as a condition to approval of the device.[5]

21 C.F.R. § 814.84(b)(1) requires that such periodic reports "[i]dentify changes described in § 814.39(a) and changes required to be reported to FDA under § 814.39(b)."

In order to prove the crime of making or submitting a materially false or misleading report as alleged in the information, the Government must establish the following elements beyond a reasonable doubt:

- That Ventak Prizm 2 DR is a medical device.
- That Guidant was a manufacturer or importer of the Ventak Prizm 2 DR.
- That Guidant submitted a report required by the FDCA with regard to the Ventak Prizm 2 DR.

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[5] As a practical matter, FDA conditions nearly all PMA approvals on the submission of these periodic reports, including with regard to the devices at issue here.

- That such report contained information that was false or misleading.
- That the false or misleading information in the report was material.

B. Count Two: Failure to Report Device Recall

Another act that is prohibited under 21 U.S.C. § 331 is:

(q)(1) the failure or refusal to . . .

> (B) furnish any notification or other material or information required by or under section 360i or 360j (g) of this title.

A notification of information required by Section 360i is found in Paragraph (f):

> (1) . . . the Secretary shall by regulation require a manufacturer or importer of a device to report promptly to the Secretary any correction or removal of a device undertaken by such manufacturer or importer if the removal or correction was undertaken—
>
> (A) to reduce a risk to health posed by the device, or
>
> (B) to remedy a violation of this chapter caused by the device which may present a risk to health.

21 C.F.R. § 806.10 requires that:

> (a) Each device manufacturer or importer shall submit a written report to FDA of any correction or removal of a device initiated by such manufacturer or importer if the correction or removal was initiated:
>
> (1) To reduce a risk to health posed by the device; or
>
> (2) To remedy a violation of the act caused by the device which may present a risk to health . . .
>
> (b) The manufacturer or importer shall submit any report required by paragraph (a) of this section within 10-working days of initiating such correction or removal.

FDA regulations define "correction" as "the repair, modification, adjustment, relabeling, destruction, or inspection (including patient monitoring) of a device without its physical removal from its point of use to some other location." 21 C.F.R. § 806.2(d). "Risk to health" is also defined by regulation:

(1) A reasonable probability that use of, or exposure to, the product will cause serious adverse health consequences or death; or

(2) That use of, or exposure to, the product may cause temporary or medically reversible adverse health consequences, or an outcome where the probability of serious adverse health consequences is remote.

21 C.F.R. § 806.2(j).

In order to prove the crime of failing or refusing to make a required report, as alleged in the information, the Government must establish the following elements beyond a reasonable doubt:

- That the Contak Renewal was a medical device.
- That Guidant was a manufacturer or importer of the Contak Renewal.
- That Guidant made a correction to the Contak Renewal.
- That Guidant undertook the correction to reduce a risk to health posed by the device.
- That Guidant failed to report the correction to FDA.

C. Maximum Penalties

The maximum penalty for each of the charged offenses is a fine of $500,000 (18 U.S.C. § 3571(c)(4)), or twice the gross gain or gross loss, whichever is greater (18 U.S.C. § 3571(d)); a special assessment of $125 per offense (18 U.S.C. § 3013(a)(1)(B)(iii)); and a five-year term of probation (18 U.S.C. § 3561(c)(2)). Additionally, criminal forfeiture may be ordered. As noted in the presentence report ("PSR"), Guidant's gross gain from the offenses based on sales figures during the relevant time is calculated to be $353,221,205. As a result, the statutory maximum fine pursuant to Section 3571(d) (twice the gross gain) is $704,442,410. [6]

[6] The alternative fine provisions of 18 U.S.C. § 3571(d) establish the statutory maximum fine by doubling the "gross gain" from the offense – that is, total revenue received – without regard to deductions or costs that are otherwise applied to determine profit, *i.e.*, "pecuniary gain." *See United States v. BP Prods. N. Am., Inc.*, 610

IV. FACTUAL BASIS FOR THE CHARGES

If this case were to proceed to trial, the Government would prove these facts beyond a reasonable doubt, as well as each of the other allegations as set forth in the information.

A. The Origins of the Government's Investigation

On October 4, 2001, J.O., a Minnesota teenager with hypertrophic cardiomyopathy[7] received a Prizm ICD to protect him from his risk of sudden death from ventricular fibrillation. While bicycling with his girlfriend in Utah in March 2005, J.O. complained that he was feeling tired, dismounted from his bicycle, and collapsed, unconscious. Despite efforts by his girlfriend and passers-by to resuscitate him, J.O. died. Post-mortem analysis of the explanted ICD revealed that it had short-circuited while attempting to provide life-saving therapy to J.O., and hence failed to rescue him from sudden death.

Several prominent physicians had been monitoring J.O.'s progress and actively sought to understand why he had died; they had viewed ICDs to be a promising treatment for patients like J.O. One of them, Dr. Barry Maron, is currently the Director of the Hypertrophic Cardiomyopathy Center at the Minneapolis Heart Institute Foundation. Another, Dr. Robert Hauser, is a senior consulting physician at the institute. Additionally, Dr. Hauser was the CEO of Guidant's predecessor, Eli Lilly's Cardiac Pacemakers, Inc. ("CPI") from 1988 to 1992. In 1992, Eli Lilly spun off its medical device business, and CPI became part of Guidant.

Drs. Maron and Hauser sought additional information from Guidant officials in the wake of J.O.'s death. Guidant's Chief Medical Officer, Dr. Joseph M. Smith, and three other Guidant executives met with Maron and Hauser in May 2005. During their presentation, the Guidant

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F. Supp. 2d 655, 683 (S.D. Tex. 2009) ("'Gross' pecuniary gain or loss simply means that the court is not to reduce the amounts to a net sum, by deducting such items as costs.").

[7] Hypertrophic cardiomyopathy is a heart disorder in which the walls of the heart muscle thicken and become stiff. It affects an estimated 600,000 to 1.5 million Americans, or approximately one in 500 people and is the most common cause of sudden cardiac death in people under age 30.

officials revealed that the company had been aware of twenty-five other cases over the previous three years in which the Prizm device had short circuited like J.O.'s. Guidant admitted that the short-circuiting problem had not been disclosed to anyone outside the company, except those individual physicians who returned devices that suffered from this failure mode.

Dr. Maron told the Guidant representatives that Guidant should communicate with physicians about the known arcing problem. Guidant refused to do so. Guidant's Chief Medical Officer, Dr. Smith, specifically told Dr. Maron during that meeting that patients were not "smart enough" to handle the information that Guidant possessed. The Guidant executives requested that Dr. Maron and Dr. Hauser not reveal the contents of their discussion. Dr. Maron's response was to tell the Guidant officials that not communicating what they knew would be "the biggest mistake they would ever make." Guidant's retort to Dr. Maron was simply, "We don't agree."

Drs. Maron and Hauser felt that it was their responsibility to communicate about the flaw in the Prizm if Guidant refused to do so and called the NEW YORK TIMES. After being contacted by the newspaper for comment on the upcoming article, Guidant issued a "Dear Doctor" letter regarding the failure of some Ventak Prizm 2 implantable defibrillators manufactured before April 16, 2002. The following day, on May 24, 2005, the front page of the NEW YORK TIMES carried the article highlighting J.O.'s death. The story reported that Guidant had known of the flaw in the ICD for three years but had not disclosed it. On June 2, 2005, the paper further reported that Guidant sold an existing inventory of flawed defibrillators after the Prizm short circuiting problem had ostensibly been fixed in 2002.

Guidant made a number of disclosures to the FDA in the wake of the massive press coverage. Between May 27, 2005 and June 6, 2005, FDA conducted a regulatory inspection of Guidant's facilities. During that inspection, the FDA inspector asked if Guidant was having

similar arcing problems with any devices other than Prizm. Only then did the company reveal that it was experiencing similar short-circuit problems with its Contak Renewal and Contak Renewal 2 devices. Following additional meetings with FDA, on June 17, 2005, Guidant issued a safety advisory on over 50,000 individual defibrillators, involving seven different device models. Three of the devices involved short-circuiting of the defibrillator and the other four involved a software memory loss. Two weeks later, FDA classified the communications with regard to the Prizm 2 and Renewal 1 and 2 devices as "Class I Recalls," the most severe of three classification levels.

The recalls and surrounding publicity prompted the Government to begin a criminal investigation into the events surrounding and leading up to Guidant's recalls of June 2005. The charges and negotiated plea agreement were the products of the evidence developed during that four-year investigation.

B. The Prizm 2 Arcing

The Prizm 2 was approved by FDA, via an approval letter, for marketing in July 2000 for "patients who have had spontaneous and/or inducible life-threatening ventricular arrhythmias and those who are at high risk for developing such arrhythmias." FDA's approval of the device was subject to the "Conditions of Approval" which were attached to the approval letter. The Conditions of Approval stated, *inter alia*:

> Before making any change affecting the safety or effectiveness of the device, submit a PMA supplement for review and approval by FDA unless the change is of a type for which a "Special PMA Supplement – Changes Being Effected" is permitted . . . .
>
> A PMA supplement must be submitted when unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures necessitate a labeling, manufacturing or device modification.

By early 2002, Guidant began receiving reports from the field of Prizm 2 devices failing due to an arc underneath the header when the devices attempted to deliver a high-voltage shock to a patient's heart. By April 2002, Guidant had notice of two events where short circuiting had occurred in the devices. At that time, Guidant was unaware that the actual cause of the arcing was chemical degradation of the polyimide insulation that surrounded the high-voltage wires underneath the header of the device. In April 2002, Guidant changed the Prizm 2 to increase the distance between the wire and the metal body of the device, and added more silicone rubber (medical adhesive) into the space underneath the header to try to prevent the observed arcing. This change to the device's design was not reported to FDA.

After a third arcing event the following month, Guidant considered the failures to be a "trend" and began more formally to investigate the failures. Part of this investigation included conducting a "Health Risk Assessment" or "HRA" of the trend. The HRA concluded that the likelihood of injury to patients from this failure mode was "very likely" and that the severity of injury associated with it was "life threatening."

On November 13, 2002, after experiencing four arcing failures, Guidant instituted a second change to the Prizm's design to correct the arcing. This change involved adding an insulation sleeve over the metal tube on the case of the device where the arcs were occurring. Guidant waited nine months to report to FDA that it had made this change to the device, and did so not in a PMA supplement, as required, but rather in its annual post-approval device report on August 19, 2003. Although Guidant's report described the methodology of the change, it did not explain why it had made the change. In fact, it categorized the change as one of several "minor manufacturing changes or other minor alterations to the device … which do not affect the safety or effectiveness of the device." These statements were materially false.

Between the time of the November 2002 change and the March 2005 death of J.O., twenty-one more arcing incidents occurred. It was not until May 2005, when Guidant learned that the NEW YORK TIMES planned an exposé on the Prizm, that it decided to communicate with physicians and FDA about the problem. Even those belated communications contained false and misleading statements, as described below.

C. The Renewal 1 & 2 Arcing

The problem of arcing underneath the header was not limited to the Prizm 2. Not long after Guidant began marketing the Contak Renewal, it began to experience similar arcing problems underneath the header of that device. Guidant was notified of the first Renewal arcing event on November 18, 2003. Guidant's Technical Services department received a call from a Guidant sales representative in the field who reported that after a patient received a shock from the device, the device reported a low shocking lead impedance through the computer that physicians use to communicate with the implanted device (called a "programmer"). The leads – a separate medical device – are the wires that connect the ICD to the heart tissue.

On or about May 8, 2004, Guidant received word of the second Renewal arcing event. Following a commanded shock in the hospital, the device reported that it had encountered an "out of range shocking impedance" on the leads. The patient underwent surgery to replace the leads, but when the physician used the same Renewal with the new leads, the warning screen again appeared, indicating that the problem was not with the leads, but rather with the Renewal pulse generator. A third arcing event was reported to Guidant a month later. Analysis of the devices confirmed that they all had arced underneath the header of the pulse generator, and that there was no problem with the leads.

The Renewal issue took a significant turn on July 5, 2004, when Guidant became aware of a patient death in Barcelona, Spain. The significance sprang not only from the fact that the patient had died, but also because the death report came from Dr. Josep Brugada, a world-famous cardiologist. On June 21, 2004, the patient, J.S., came to Dr. Brugada's clinic for a regularly scheduled follow-up appointment. Upon interrogation of his device, the programmer displayed a yellow warning screen, which warned of low shocking lead impedance, and instructed the operator to "check lead integrity."

Dr. Brugada, along with the local Guidant field representative, thoroughly investigated the leads over the course of several hours. Finding no problem with the leads, Dr. Brugada sent J.S. home, where, a week later, he suffered a cardiac arrest and died. Analysis of his Renewal device found that the battery had been completely depleted due to arcing underneath the header.

Now confronted with four arcing incidents in the Renewal family of devices, with one resulting in the death of a patient, Guidant formally opened "Trend 04037," entitled "Renewal 1-2 Feedthrough Wire Arcing to Case" on July 16, 2004. All four events presented with the programmer displaying the yellow shorted shocking lead warning screen, directing the physician to "check lead integrity." This yellow screen was the hallmark of the shorting problem. Moreover, as Guidant's internal documents establish, Guidant realized that although the short circuit was occurring within the pulse generator, the device failures' "presentation is no different than for a shorted lead" and that "neither pacing nor shocking therapy may be available." Guidant knew, therefore, as of July 2004, that the warning screen was false and misleading. On July 20, 2004, Guidant initiated a corrective action similar to the action taken in April 2002 to mitigate the Prizm arcing. As with the April 2002 addition of medical adhesive underneath the

header of the Prizm, Guidant did not promptly notify FDA of this manufacturing change to the Renewal, a change that was undoubtedly made to mitigate the arcing problem.

During the same time frame, on July 22, 2004, Johnson & Johnson's ("J&J") Worldwide Chairman for Medical Devices met with Guidant's CEO to explore the possible acquisition of Guidant by J&J. The two companies signed a confidentiality agreement two weeks later.

Four weeks later, on August 25, 2004, the Guidant committee responsible for assuring the health and safety of patients using Guidant's products directed that all shipments of Renewals from the factory be stopped immediately "due to the severity of the issue, and the fact that it appears to present itself after multiple shocks." The health risk assessment completed two days later categorized the Renewal trend as "life threatening" with the overall category as "Red" – the most serious category of health risk. The "Core Team" of product engineers and other specialists assigned to investigate the trend concluded that same day that the Renewal would have to be recalled if they could not determine the root cause of the arcing within the week.

By September 7, 2004, the Core Team understood why the Renewal devices were failing. The team became aware of a research paper that demonstrated that polyimide tubing – the insulator tubing on the high voltage wires underneath the header on both the Prizm and Renewal – can degrade in warm, moist environments such as that found within the human body. By September 11, 2004, Guidant realized that hydrolytic degradation of polyimide insulation was also the root cause for the arcing in the Prizm 2.

By mid-September 2004, Guidant was therefore aware that both the Renewal and the Prizm 2 were subject to catastrophic failure due to arcing caused by hydrolytic degradation of polyimide insulation. On September 20, 2004, a Guidant employee drafted the first version of a "Dear Doctor" letter to be sent to physicians regarding the arcing. This letter was never sent.

In September 2004, Guidant was aware of five Renewal arcing incidents. The engineers believed that there were only two ways to prevent the arcing: redesign the header or change the insulation from polyimide to something else. The company decided to continue the stop ship order due to the severity of the issue. Yet the company also decided explicitly to "continue to sell" the defective devices that were already in inventory and had been distributed across the country. The evidence establishes that the basis for Guidant's decision was that halting device implants would have triggered a recall and FDA scrutiny.

By November 2004, Guidant's analysis showed that the rate of clinical arcing failures would increase as the devices aged while implanted and that it was expected that one to four percent of the Renewal devices would short-circuit. That same month, Guidant submitted a 30-day notice of "manufacturing process change" to FDA to fix the Renewal arcing.[8] In it, Guidant told FDA that the reason for the manufacturing change was to "provide a more consistent anchoring of components during subsequent assembly operations" and to "create a more repeatable process." Although the document vaguely describes the arcing on Page 6, it omitted material information that only Guidant knew: that the root cause of the damage to the insulation (*i.e.*, hydrolytic degradation – a property of the insulation itself that made *all* the implanted Renewal devices susceptible to failure), that the rate of failure was projected to greatly increase over time, that one person had died, and that Guidant considered the problem serious enough to order the factory to stop building the devices.

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[8] At that time, a 30-Day notice received less scrutiny at FDA than other requests for changes. The lack of review stems from the fact that this type of submission is designed to review manufacturing process changes (as opposed to changes to the device's design) "intended to: reduce manufacturing and/or labor cost, reduce manufacturing time, reduce waste, [or] compensate for a change in suppliers of raw material or components." *30-Day Notices and 135-Day PMA Supplements for Manufacturing Method or Process Changes, Guidance for Industry and CDRH*, FDA Center for Devices and Radiological Health. A 30-day notice is not appropriate for submitting changes to a device design that affects the device's safety or efficacy.

Guidant followed the 30-day notice with a request for "Real Time Review" of a PMA Supplement requesting FDA approval for additional "minor changes" to the Renewal a week later. In that submission, which was to further modify the device to fix the arcing problem, Guidant told FDA that the "minor" modifications it proposed to the header were "not being done to correct device flaws that threaten patient safety." Rather, Guidant told the FDA, the changes were being proposed "to improve process throughput."

On or about December 1, 2004, Guidant became aware of the ninth Renewal arcing event. Two weeks later, on or about December 14, 2004, the leader of the Core Team became convinced that Renewal should be recalled because its performance was "not as expected." The same day the Core Team leader was preparing his recommendation that the company recall the Renewal, Guidant and J&J executed a merger agreement in a deal that was valued at approximately $25 billion. At the time, J&J characterized the Guidant transaction as the biggest business deal in its 118-year history.

With the ink barely dry on the merger agreement, the engineers investigating the Renewal trend agreed to recommend to senior management to carry out a formal recall of the Renewal. On January 7, 2005, the Core Team recommended a "Dear Doctor" letter that clearly laid out what Guidant understood about the arcing problem, how it presented (i.e., through the display of the yellow warning screen), and directed physicians to replace the *pulse generator* if the yellow screen was displayed.

In addition to communicating about the problem, the Core Team agreed to recommend that "remaining shelf devices be pulled," that "the programmer screen be updated to clarify physician instructions," and that the "labeling be clarified." Additionally, they drafted a

presentation for FDA to disclose the arcing problem and in which Guidant would tell the agency that "unanticipated deaths could reasonably be expected to occur."

The senior management committee responsible for device recalls at Guidant, the "Officer Escalation Group," discussed the Core Team's recommendations on the next business day, January 10, 2005. Guidant's senior management rejected the engineers' recommendations. The fact that Guidant's senior management refused to pull back the remaining Renewals on hospital shelves particularly disturbed a physician member of the Core Team, who urged that the flawed devices in inventory no longer be implanted. His advice, however, went unheeded.

Guidant's director of product performance reporting and quality assurance attended these meetings with the senior management. He contemporaneously memorialized the discussions in a notebook:

> Can we go get devices? Would prefer generic letter. ***Can we do this quietly without focusing on R1/R2 [Renewal 1 and 2]?***

Another Guidant employee suggested during a meeting that Guidant could remove the shelf devices ostensibly "for testing" without triggering a formal recall.

Rather than conducting a formal recall, Guidant decided to communicate with physicians using what the company characterized as the "least aggressive" form of communication available to it – a "Product Update." The planned Product Update was described in Guidant documents as discussing "tests available to check shock lead integrity . . . but makes no mention of Renewal or the event in which a patient was sent home after a yellow screen was observed [and subsequently died]."

The removal of the devices "for testing," combined with the distribution of a "generic product update" on the yellow warning screen and the modification of the device's design to

prevent future arcing incidents comprised Guidant's mitigation plan for the Renewal arcing – a plan that avoided any disclosure of the problem to the public or the Government regulators.

In early March 2005, Guidant distributed the "Product Update: Shorted Shock Lead Warning Screen" to physicians by sending it to them directly – an extraordinary step not normally taken because Product Updates were not meant to communicate about safety hazards, but rather were "used to train/educate health care professionals and Guidant field personnel regarding specific features and operating characteristics of Guidant products that are described in current device labeling."

Accompanying the Product Update, Guidant sales representatives were provided with a set of "Q&A's" – a scripted list of questions and answers created to "help prepare [sales representatives] for conversations with [their] physicians regarding the Product Update." Like the Product Update itself, the Q&A's mentioned nothing about the arcing problem. Rather the Q&A's stated that the Product Update was ***not*** a recall or safety alert, but rather a "normal Product Update … to ensure that physicians are fully educated on the latest information with regard to the management of our devices." Moreover, the sales representatives were instructed to tell physicians that there was no problem with the Renewal or Prizm devices. The denial of problems was reiterated in the Q&A's, which told Guidant representatives not to expect a "fix" because "***nothing is broken***."

Even when confronted with a direct question from an FDA official in March 2005 as to whether the Product Update represented a recall or correction, Guidant responded with false and misleading information. In response to that direct question, in an April 1, 2005 letter to FDA, Guidant sought to lull the agency into believing that the Product Update was not related to any risk to patient health:

> Product Updates, and specifically the issue dated February 2005, are utilized when the devices are performing as intended and are not being removed from the market. Product updates do ***not*** communicate a new or escalating issue, nor do they require that action be taken for patients with Guidant devices. Product Updates are used when there are no new or increased risks to patient health due to device performance and there are no changes to the device labeling. Product Updates do not meet the definition of a recall or a correction but rather are communications created to highlight or clarify an existing device operating characteristic.

On April 27, 2005, Guidant indicated in an internal document that it contemplated no further corrective or remedial action with regard to the Renewal arcing problem.

D. Public Disclosure of the Problem

The story of the arcing in the Renewal and Prizm devices might well have ended there if not for the publicity surrounding the death of J.O. When Guidant learned that Drs. Hauser and Maron had communicated about the Prizm arcing to some of their colleagues, Guidant developed what it dubbed the "Prizm 2 Action Plan." This plan called for Guidant to attempt to contact any physician that Drs. Hauser and Maron had told about the arcing, but to otherwise keep silent about the problem unless certain "triggers" occurred. These triggers included: if Guidant determined that "knowledge of this incident has escaped outside of the physicians notified by the Hauser email" and if Guidant were to "receive inquiries on this from the FDA."

The day before the newspaper story ran, on May 23, 2005, Guidant made an effort to preempt it by sending a "Dear Doctor" letter to physicians. Although the letter disclosed that some Prizm 2 devices had failed, it mentioned nothing about polyimide degradation and continued to minimize the seriousness of the problem, characterizing it as a "rare and unpredictable . . . random component failure" when in fact, Guidant knew the root cause, mechanism, and predicted rate of failure. Moreover, as it appeared that the NEW YORK TIMES reporter knew nothing about the related Renewal failures, Guidant's Dear Doctor letter omitted

any mention of the arguably more serious Renewal arcing. The Q&A document for sales representatives that was distributed with this letter falsely stated outright that the arcing affected **only** the Prizm 2 devices. "All other Guidant products," the sales representatives were told, "are not susceptible to this particular failure mode." Further, any relationship between arcing and the Product Update was disavowed with the pithy statement, "It is not related."

The day before the article's publication, Guidant called FDA to "notify FDA of Guidant's plan to communicate with physicians in response to communications by sources other than Guidant regarding a specific failure mode observed in certain Prizm 2 DR ICDs." A meeting and teleconference was scheduled for the following day at FDA's headquarters. During that meeting, on May 24, 2005, an FDA official explicitly asked the Guidant representatives if any other device other than Prizm 2 was involved with this failure mode. Guidant steadfastly denied that any device other than Prizm 2 was involved.

On Friday, May 27, 2005, FDA investigators began a "focused inspection" of Guidant. Only days later, on Tuesday, May 31, 2005, Guidant learned that a patient in California, D.S., had died the previous evening when her implanted Renewal shorted and failed to provide therapy. This was the fifteenth Renewal arcing event of which Guidant became aware. The following morning, in response to a question from the FDA inspector looking into the Prizm arcing, Guidant for the first time fully disclosed to FDA that they were experiencing the same arcing problem with the Renewal family of devices.

On June 17, 2005, after advising FDA, Guidant issued "Dear Doctor" letters branded "URGENT MEDICAL DEVICE SAFETY INFORMATION AND CORRECTIVE ACTION," recalling the Prizm 2 DR and the Renewal 1 and 2. Nearly all the information contained in these letters was known to Guidant for at least ten months, including the connection between the

yellow warning screen and the Renewal arcing. FDA classified both recall communications as "Class I" recalls, the most serious classification, indicating "a situation in which there is a reasonable probability that the use of or exposure to the violative product will cause serious adverse health consequences or death."

V. THE SENTENCING CONSIDERATIONS

The United States maintains that the agreed-upon sentence takes into account Guidant's conduct under 18 U.S.C. §§ 3553 and 3572, and the United States Sentencing Guidelines. The agreed-upon sentence reflects the breadth and length of the company's criminal conduct, including relevant conduct relating to the charged false statements and failure to report the correction.

The Government generally agrees with the Sentencing Guidelines analysis contained in the PSR.[9] As the PSR correctly notes, the fine provisions of U.S.S.G. §§8C.2.2 through 8C2.9 do not strictly apply in this case. However, the Government agrees that computing the guideline fine range under those provisions is useful to determine an appropriate fine and for the application of the factors under 18 U.S.C. §§ 3553 and 3572.

The Guidelines require the computation of the "base fine" based on the "pecuniary gain" to the defendant. To determine the "pecuniary gain" (before-tax profit) to Guidant from the offense, using data provided by Guidant, the Government calculated the number of Prizm 2 and Renewal devices sold in the United States during the relevant time. The Government and Guidant then estimated the profit margin Guidant enjoyed from the sale of these devices. This profit margin was applied against the average selling price for each device (as reported by

[9] However, the Government respectfully disagrees with the PSR's conclusion that there was no "loss" from the conduct. PSR ¶ 94. Rather, computation of the total amount of loss to all parties is not reasonably feasible and would unduly complicate or prolong the sentencing process. As a result, the Government agrees that the base fine amount should be based on Guidant's pecuniary gain rather than loss to others.

Guidant. The Government and Guidant agreed during plea negotiations that, using this methodology, the "pecuniary gain" (before-tax profit) to Guidant from the offense was $144,410,693. This figure becomes the "base fine" under the Guidelines, which is then multiplied by a factor determined by the defendant's culpability score. U.S.S.G. § 8C2.4.

The Government agrees with the Probation Office's computation of Guidant's culpability score. The PSR correctly adds five points to the base culpability score of five because the Guidant had more than 5,000 employees and high-level personnel participated in the offense. U.S.S.G. § 8C2.5(b)(1)(A).

An additional two points are correctly added because of Guidant's prior criminal history. U.S.S.G. § 8C2.5(c)(2). Specifically, in June 2003, Guidant's subsidiary, Endovascular Technologies, Inc. ("EVT"), was convicted in the Northern District of California of nine felony counts of violating the FDCA and one felony count of making false statements to FDA, which resulted in civil and criminal penalties totaling $92.4 million. In that case, Guidant's subsidiary pleaded guilty to covering up thousands of device malfunctions that resulted in at least 12 deaths and dozens of invasive surgeries. Both EVT and Guidant entered into a five-year corporate integrity agreement with the Department of Health and Human Services as a result of that case. As a result, Guidant was supposed to be operating under enhanced corporate compliance safeguards at the same time the Prizm and Renewal misconduct occurred.

One point is subtracted due to Guidant's acceptance of responsibility for the offense. U.S.S.G. § 8C2.5(g)(3). The resulting culpability score is 11. This culpability score yields a multiplier of 2.0 to 4.0, which is applied to the base fine to determine the Guidelines fine range. This results in a Guidelines fine range of $288,821,386 to $577,642,772.

The total criminal penalty agreed to by the parties in the plea agreement was $296,041,926 (Forfeiture: $42,079,675; Fine: $253,962,251). This total is within the Sentencing Guidelines' fine range and represents a just punishment, taking into account all the factors required by 18 U.S.C. §§ 3553 and 3572.

Given the nature and circumstances of the offense, and history and characteristics of the defendant, the criminal fine agreed to by the parties reflects the seriousness of the offense and the previous felony violations of the FDCA committed by Guidant's subsidiary, EVT. Guidant's evasion of regulatory oversight created a serious risk to public health and safety. Additionally, Guidant prevented physicians from exercising their own medical judgment by withholding important information from physicians and their patients it deemed they were not "smart enough" to handle.

The large criminal fine promotes respect for the law and regulatory framework established by the FDA. The proposed sentence will deter Guidant, and its corporate parent, Boston Scientific, from further unlawful efforts at circumventing agency oversight. A criminal fine of this magnitude, coupled with the massive publicity that surrounded the recalls, will also serve as deterrence to other medical device manufacturers who might be tempted to shirk their responsibilities under the law when confronted with a risk to public health and safety caused by their product.

On April 27, 2010, the Court declined to accept the proposed plea agreement as written because the plea agreement did not address probation and it failed to adequately discuss where the "fine and forfeiture funds would go." *United States v. Guidant LLC*, 708 F. Supp. 2d 903, 922 (D. Minn. 2010). Those two issues are discussed below.

VI. PROBATION

Although the original plea agreement between the parties did not contemplate a term of probation, the Court has made clear that it believes a term of probation is appropriate in this case.[10] *See United States v. Guidant LLC*, 708 F. Supp. 2d. 903, 915-19 (D. Minn. 2010). In accordance with its agreement, the Government does not advocate for any penalty beyond what the plea agreement contemplates.

VII. FORFEITURE

The Court indicated in its April 27 opinion that the "record is not entirely clear as to how the forfeited amount was calculated." *Id.* The forfeiture component of the information arises from the FDCA's provision for seizing misbranded medical devices. 21 U.S.C. § 334. These proceedings are by their nature classic civil forfeiture proceedings. Under federal forfeiture law, the Government can pursue criminal forfeiture in any case where the defendant is charged with a violation of an Act of Congress where civil forfeiture is authorized. *See* 28 U.S.C. § 2461(c) (allowing criminal forfeiture where the defendant is charged "in a criminal case with a violation of an Act of Congress for which the civil or criminal forfeiture of property is authorized"). Thus, because civil forfeiture is authorized by the FDCA, criminal forfeiture is available to the Government.

[10] As of December 2009, Boston Scientific is already operating under enhanced government supervision, having entered into a five-year corporate integrity agreement ("CIA") with the Department of Health and Human Services Office of Inspector General ("HHS/OIG"). The CIA is part of a $22 million settlement of charges brought in the District of Massachusetts that the company engaged in an illegal kickback scheme with physicians. The CIA is available at http://oig hhs.gov/fraud/cia/agreements/boston_scientific_corporation_12232009.pdf and requires that Boston Scientific conduct internal and external monitoring, train its employees, report regularly to HHS/OIG and fulfill other obligations as set forth in the agreement. The CIA also requires that Boston Scientific notify HHS/OIG of any "ongoing investigation or legal proceeding known to Boston Scientific's senior management conducted or brought by a U.S.-based governmental entity or its agents involving an allegation that Guidant/CRM has committed a crime or has engaged in fraudulent activities." HHS/OIG must also be notified of any "matter brought to the attention of Boston Scientific's senior management … relating to conduct of Guidant/CRM that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program."

Guidant has pleaded guilty in Count 2 of the information to failing to report its recall of the Renewal as required in 21 U.S.C. § 360i(g). Guidant's failure and refusal to make that required report rendered all implanted Renewals manufactured prior to the corrective action of July 20, 2004, misbranded as a matter of law. 21 U.S.C. § 352(t)(2) (deeming device misbranded if "there was a failure or refusal … to furnish any material or information required by or under section 360i of this title respecting the device"). Because the misbranded Renewal devices were no longer available for seizure or destruction, having been implanted, the Government can seek substitute assets. *See* 28 U.S.C. § 2461(c) (the procedures set forth in 21 U.S.C. § 853 apply to this criminal forfeiture); 21 U.S.C. § 853(p) (allowing the forfeiture of substitute assets if the items subject to forfeiture are no longer available).

To determine the per unit value of implanted devices, the Government used the scrap value Guidant had utilized for Renewals during the relevant time: $4,675.[11] Thus, the scrap value of the 9,001 devices manufactured and sold in the United States prior to July 20, 2004 yielded the forfeiture amount of $42,079,675.

As mandated by statute, the forfeited money will be deposited into the Department of Justice Assets Forfeiture Fund. If not used for victim remission and restoration, the money is used to pay any necessary expenses associated with forfeiture operations such as property seizure, detention, management, forfeiture, and disposal. The Fund may also be used to finance certain general investigative expenses. The criteria used for disbursements from the Fund are delineated in 28 U.S.C. § 524(c).[12]

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[11] "Scrap Value" is defined by various sources as "the amount that may be realized if property is sold for its material content, as opposed to further productive use;" "The minimal worth of an object. The limit of the depreciated value."

[12] For example, the Fund may be used to pay awards for information or assistance directly relating to violations of the criminal drug laws of the United States and "for equipping for law enforcement functions of any Government-owned or leased vessel, vehicle, or aircraft available for official use." 28 U.S.C. § 524(c).

Pursuant to 42 U.S.C. § 10601, with a few exceptions not relevant here, "all fines that are collected from persons convicted of offenses against the United States" are deposited into the federal Crime Victims Fund. The fund is used to support various federal, state, and tribal crime victim assistance programs. This includes funding support for, *inter alia*, grants to states for victim assistance[13] and victim compensation,[14] training and technical assistance to improve and enhance the professional skills and expertise of victim service providers, victim-witness coordinators in U.S. Attorneys' Offices, FBI victim specialists, the Federal Victim Notification System, and grants under the Children's Justice Act to improve the investigation and prosecution of child abuse and neglect cases in American Indian and Alaska Native communities. In addition, any surplus funds may be used to replenish the Antiterrorism Emergency Reserve, which funds emergency expenses and other services for victims of terrorism or mass violence, both here and abroad.

VIII. CONCLUSION

In accordance with its Plea Agreement, the United States respectfully recommends and requests that the Court impose a criminal fine in the amount of $253,962,251 and order criminal forfeiture in the amount of $42,079,675.

Dated this 4th day of January, 2011.

[13] Crime victim assistance includes, but is not limited to: crisis intervention, emergency shelter, emergency transportation, counseling, and criminal justice advocacy.

[14] Crime victim compensation is a direct reimbursement to (or on behalf of) a crime victim for, *inter alia*, medical costs, funeral and burial costs, mental health counseling, lost wages, or loss of support.

Respectfully submitted,

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